OIPE JC76 FEB 05 2003 PATENT & TRADEMARK OFFICE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Harrington *et al.*

Appl. No: 09/484,895

Filed: January 18, 2000

For: **Compositions and Methods for Non-Targeted Activation of Endogenous Genes**

Art Unit: 1636

Examiner: Nguyen, Q.

Atty. Docket: 0221-0003G

RESPONSE UNDER 37 C.F.R. § 1.111

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This reply is in response to the Office Action dated January 15, 2003. In the Office Action, the Examiner stated that the Applicant's corrected sequence listing and CRF filed November 1, 2002, failed to comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures under 37 C.F.R. §§ 1.821 – 1.825.

REMARKS

Reconsideration of this Application is respectfully requested. In the Office Action, the Examiner states that the application fails to comply with the sequence listing requirements because, according to the Examiner, "Page 111, line 10 contains the

structure having the sequence $5'$-$(dT)_{10-30}$-PrimerX-N_{0-6}-TTTATT-$3'$ has not been

assigned a SEQ ID NO." Applicants respectfully traverse.

Section 1.821 of Title 37 of the Code of Federal Regulations specifically states:

> (a) Nucleotide and/or amino acid sequences as used in Secs. 1.**821**
> through 1.825 are interpreted to mean an unbranched sequence of four or
> more amino acids or an unbranched sequence of ten or more nucleotides.
> Branched sequences are specifically excluded from this definition.
> Sequences with fewer than four specifically defined nucleotides or amino
> acids are specifically excluded from this section. ``Specifically
> defined" means those amino acids other than ``Xaa" and those
> nucleotide bases other than ``n" defined in accordance with the World
> Intellectual Property Organization (WIPO) Handbook on Industrial
> Property Information and Documentation, Standard ST.25: Standard for the
> Presentation of Nucleotide and Amino Acid Sequence Listings in Patent
> Applications (1998), including Tables 1 through 6 in Appendix 2, herein
> incorporated by reference...

> ... (1) Nucleotides: Nucleotides are intended to embrace only those
> nucleotides that can be represented using the symbols set forth in WIPO
> Standard ST.25 (1998), Appendix 2, Table 1. Modifications, e.g.,
> methylated bases, may be described as set forth in WIPO Standard ST.25
> (1998), Appendix 2, Table 2, but shall not be shown explicitly in the
> nucleotide sequence...

In the present case, the sequence in question is a non-contiguous sequence of variable

length, which has an ambiguous section in the middle (PrimerX) that cannot be

incorporated into a sequence listing. The entire structure is really a formula for a genus

of sequences. This formula has only six defined nucleotides (TTTATT), which, by

themselves are not required to have a SEQ ID NO. The formula also contains two

hypervariable regions $((dT)_{10-30}$ and N_{0-6}) and an ambiguous variable region (PrimerX)

which is defined in the specification as <u>any</u> nucleotide sequence that can be used to

subsequently PCR amplify target nucleic acid molecules. (Page 111, lines 11-13)

Applicants' formula does not fit within the definition of "nucleotides" in section 1.821

(a)(1) because PrimerX cannot be defined in the WIPO Standard ST.25 (1998). There is no symbol for such a variable in the standard or in PatentIn software. As such, according to § 1.821, this formula is correctly excluded from Applicants' sequence listing. Moreover, one of the purposes of the sequence listing requirement was that it would allow Examiners and others to electronically search public and private databases for prior art sequence information. Applicants' formula cannot be searched in this manner as PrimerX represents an unknown variable and makes a search meaningless. Therefore, such a sequence formula cannot have been contemplated to be included within the requirements for the sequence listing.

CONCLUSION

It is believed that a full and complete response has been made to the Notice and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

SHANKS & HERBERT
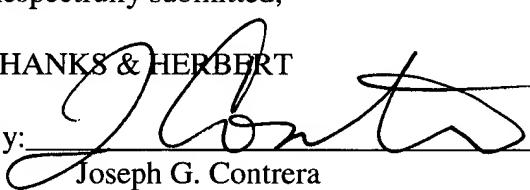
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